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No. 92-102

# In the Supreme Court of the United States

OCTOBER TERM, 1992

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WILLIAM DAUBERT AND JOYCE DAUBERT, ET AL.,
PETITIONERS

*v.*

MERRELL DOW PHARMACEUTICALS, INC.

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*ON WRIT OF CERTIORARI TO*
*THE UNITED STATES COURT OF APPEALS*
*FOR THE NINTH CIRCUIT*

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## BRIEF FOR THE UNITED STATES AS AMICUS CURIAE SUPPORTING RESPONDENT

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## QUESTION PRESENTED

Whether evidence of causation proffered by petitioners failed to meet the requirements of the Federal Rules of Evidence concerning the admissibility of expert scientific testimony.

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## BRIEF FOR THE UNITED STATES AS AMICUS CURIAE SUPPORTING RESPONDENT

## INTEREST OF THE UNITED STATES

The United States is vitally interested in the issue of the admissibility of expert testimony concerning scientific theories in federal court. The federal government is a party to a far greater number of civil cases "on a nationwide basis than even the most litigious private entity." *United States* v. *Mendoza*, 464 U.S. 154, 159 (1984). In addition, the government is solely responsible for the enforcement of federal criminal laws. Because of the great diversity of its civil and criminal litigation, the federal government finds itself supporting the admission of scientific theories in some cases while opposing their admission in others. The federal government is therefore interested in a principled approach to resolution of the question presented in this case.

## STATEMENT

1. This case involves the admissibility of expert opinion testimony concerning epidemiology. Epidemiology, the study of disease distribution in human populations, is directed to determining factors that are likely to cause disease. To the extent pertinent here, epidemiologists use statistical methods for two distinct purposes. First, they use them to uncover statistical *associations* between risk factors and the incidence of disease. Second, because the mere existence of a statistical association between two variables does not mean that one *caused* the other, the researcher can attempt to draw conclusions about causation based on the strength of the relationship and other factors. See generally M. Dore, *A Commentary On The Use Of Epidemiological Evidence In Demonstrating Cause-In-Fact*, 7 Harv. Envtl. L. Rev. 429, 431-433 (1983); see also *In re Agent Orange Product Liability Litigation*, 611 F. Supp. 1223, 1231 (E.D.N.Y. 1985) (Weinstein, J.), aff'd, 818 F.2d 187 (2d Cir. 1987). Because the statistical concepts used in such studies are helpful to an understanding of the record in this case, we review them briefly here.

Researchers conducting epidemiological studies will ordinarily begin by identifying a group of persons and determining if those persons have been exposed to the suspect factor (in this case, Bendectin). Researchers will then determine the extent to which the disease outcome occurs in the each of the two subsets—the exposed and the non-exposed groups—of the population being examined. This type of analysis will provide the rates of incidence (number of cases within that defined population) for the exposed and non-exposed persons. Using those figures, a researcher can calculate the "Relative Risk" statistic. Relative Risk is a ratio of the incidence rate among those exposed in comparison to the incidence rate among those not exposed to the suspect factor. Thus, when a Relative Risk equals 1.00 there is no difference between the rates of disease occurring between the exposed group and the non-exposed group. A Relative Risk



figure greater than 1.00 (*e.g.*, 1.30) indicates that the incidence of a disease is higher among the group of persons exposed to the suspect factor than among the group that was not exposed. Conversely, a Relative Risk of less than 1.00 (*e.g.*, 0.90) indicates that the incidence of a particular disease is lower among the persons exposed to the suspect factor, when compared with those not exposed. See *Turpin* v. *Merrell Dow Pharmaceuticals, Inc.*, 959 F.2d 1349, 1353 n.1 (6th Cir.), cert. denied, 113 S. Ct. 84 (1992); *DeLuca* v. *Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941, 947 (3d Cir. 1990); *Brock* v. *Merrell Dow Pharmaceuticals, Inc.*, 874 F.2d 307, 311-312, modified, 884 F.2d 166 (5th Cir. 1989), cert. denied, 494 U.S. 1046 (1990).

Once a Relative Risk figure is obtained, the epidemiologist must determine the likelihood that the figure could have arisen due to chance alone. That determination is necessary because, owing entirely to chance, a disease will not typically occur at *precisely* the same rate among any two groups of healthy people.[1] The procedure by which the effects of chance are excluded involves the application of basic statistical principles with which this Court is familiar. See, *e.g.*, *Hazelwood School District* v. *United States*, 433 U.S. 299, 308-312 (1977); *Castaneda* v. *Partida*, 430 U.S. 482, 495-499 & nn.16-18 (1977). The

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[1] Thus, it is impossible to say from the mere fact that the Relative Risk statistic is somewhat above or below 1.0 whether there is any real relationship between the suspect factor and the disease. The situation is analogous to obtaining more of one number than another when a die is rolled a dozen times—that may well be the result of random chance, rather than the die being "loaded." The principle is also exemplified by another quintessential example of the operation of chance—the tossing of a fair coin. While the chance that the coin will turn up heads is always 50 percent for each throw, the number of heads that results from numerous throws will not necessarily be equal to half the total number of throws. For a small number of throws the departure from the expected value (*i.e.*, half), may be quite large relative to the total number of throws. See D. Freedman, R. Pisani, R. Purves & A. Adhikari, *Statistics* 248 (2d ed. 1991).

fundamental point is both simple and intuitive. In any purely random drawing "the results * * * are likely to fall in the vicinity of the expected value." *Castaneda* v. *Partida*, 430 U.S. at 496 n.17. In fact, the distribution of the results of such a random drawing around the expected value can be predicted by statistical principles. Approximately 68 percent of the results will cluster within one standard deviation of the expected value, while approximately 95 percent will cluster within two standard deviations. See D. Freedman, R. Pisani, R. Purves & A. Adhikari, *Statistics* 63-82 (2d ed. 1991). If an observer is trying to determine whether an outcome (such as the results of tossing a coin or casting a die) is consistent with the operation of chance, or whether something else may be at work (for example, the coin may not be "fair" or the die may be "loaded"), he should be unwilling to rule out chance unless the distribution resulting from the experiment differs sufficiently from the distribution predicted by chance. See, *e.g.*, *Castaneda* v. *Partida*, 430 U.S. at 497 n.17 ("As a general rule for such large samples, if the difference between the expected value and the observed number is greater than two or three standard deviations, then the hypothesis that the jury drawing was random would be suspect to a social scientist."); *id.* at 494 n.13.

These principles of probability can be adapted to the context of drawing samples from a population and arriving at conclusions about that large population based on what is learned from the sample. An epidemiologist wants to compare the incidence of fetal malformation in the exposed and non-exposed groups. The problem might be analogized roughly to an experiment designed to learn whether a pair of dice are "loaded" by comparing the distribution of the outcomes they produce to the distribution of the outcomes produced by a second pair of dice, which we know to be exquisitely balanced. A practical problem in designing the epidemiological experiment is that the actual populations of exposed and non-exposed persons are too large and too indeterminable to be compared directly with one another. Because it is impractical to study *every* member of the exposed and the non-exposed groups, learning the incidence of malformation in each of the two groups necessarily involves "sampling."



A characteristic of sampling is that the incidence of a quality in the sampled group is not necessarily *identical* to the incidence of that characteristic in the general population. See *DeLuca* v. *Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d at 946. But the result is likely to be "in the vicinity," *Castaneda* v. *Partida*, 430 U.S. at 496 n.17, of the number produced by the sampling technique. Thus, if sampling should show that four mothers out of one thousand in the non-exposed group gave birth to deformed children, while six exposed mothers out of one thousand from the exposed group did so, the researcher cannot assume that each of these figures necessarily represents the actual incidence of fetal malformation in the two groups sampled. But he can estimate that the true value for each group is somewhere "in the vicinity" of that shown by the sample. To calculate *how close* the real population percentage is likely to be to the figure observed in the sample, statisticians use "confidence intervals."

A confidence interval is a way of graphically representing the probability that a sampling result was due to something other than chance. The range of possible "true" values clusters around the figure obtained by sampling. By choosing a sufficiently wide interval of values around the figure obtained by sampling, the researcher can be reasonably confident that the true population incidence will be captured in that interval. For example, since there is a 95 percent chance that the "true" value lies within two standard deviations of the sample figure, that particular "confidence interval" (*i.e.*, two standard deviations) is therefore said to have a "confidence level" of about 95 percent.[2] It is important to

[2] A random sampling from the population would technically be measured by its "standard error" rather than by its "standard

recognize that the real population standard in which the researcher is interested—*e.g.*, what percentage of Bendectin users and nonusers in the actual population gave birth to children with limb malformations—is unchanging. While it is customary (and, in many cases, easier) to speak of "a 95 percent chance" that the actual population percentage is within two standard deviations of the figure obtained from the sample, "the chances are in the sampling procedure, not in the parameter." D. Freedman, R. Pisani, R. Purves & A. Adhikari, *supra*, at 351; *id.* at 397. What the short-hand expression actually means is that if the sampling from the general population were repeated numerous times, the "real" population figure would be within the confidence interval 95 percent of the time. *Id.* at 351. The "real" figure would be outside that interval the remaining five percent of the time.

Having obtained a sample figure for each of the exposed and non-exposed populations, the researcher may compute the Relative Risk statistic by dividing the former by the latter. Evaluating the meaning of the figure obtained entails recognition that both the numerator and the denominator will often be mere approximations of the real world data. The fact that the Relative Risk statistic differs from the "normal" value of 1.0 will therefore often reflect nothing more than the chance variability inherent in each of the two sampling procedures. Specifically, if the expected "normal" value of 1.0 is within the 95 percent confidence interval of the Relative Risk statistic obtained in the study, the result of the study is close enough to the normal value as to be expected simply from chance in a large number of cases. If the 95 percent confidence interval does *not* include the expected value for the Relative Risk statistic, a statistically significant *association* has been identified.

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deviation." For present purposes, the difference in terminology is not significant because the distribution of the outcomes is the same as for other random drawings.



A statistically significant *association* does not by itself tell the researcher anything definitive about *causation* even as a general matter, much less in the case of a particular tort plaintiff. "Because we often may not understand the mechanisms by which a drug causes human injury, epidemiological correlation alone does not constitute proof of causation." J. Sanders, *The Bendectin Litigation: A Case Study in the Life Cycle of Mass Torts*, 43 Hastings L.J. 301, 329 (1992); Dore, *supra*, 7 Harv. Envtl. L. Rev. at 431; accord K. Hall & E. Sibergeld, *Reappraising Epidemiology: A Response To Mr. Dore*, 7 Harv. Envtl. L. Rev. 441, 445 (1983). Thus, even after finding a statistically significant association, researchers must turn to other factors to draw inferences about causation, including a study of the temporal relationships involved (*i.e.*, cause must precede effect), the strength of the correlation (*e.g.*, the higher the strength of the association the less likely it is that other factors are involved), the coherence of the evidence (*e.g.*, taking higher doses of a drug should increase likelihood of observable effects), and the consistency on replication (*i.e.*, multiple replications diminish the probability that results are spurious or the product of methodological flaws). See Sanders, *supra*, 43 Hastings L.J. at 329-330. It is from that combination of analyses that experts then attempt to draw conclusions about the likelihood of causation.

2. Petitioners William and Joyce Daubert brought this products liability action, individually and as Guardians Ad Litem for their infant son, Jason Daubert, against Respondent Merrell Dow Pharmaceuticals, Inc. (Merrell Dow) in the Superior Court for San Diego County, California. Petitioner Anita De Young also sued Merrell Dow in the same court, individually and as Guardian Ad Litem for Eric Schuller. Petitioners all alleged that Bendectin, a prescription anti-nausea drug formerly manufactured by Merrell Dow for pregnant women, caused the limb reduction birth defects from which Jason Daubert and Eric Schuller suffer. Merrell Dow removed both cases to

the United States District Court for the Southern District of California, where they were consolidated.

Following discovery, Merrell Dow moved for summary judgment on the issue of causation. relying, *inter alia*, on the affidavit of Dr. Stephen H. Lamm, a physician and epidemiologist. After reviewing all published epidemiological studies concerning Bendectin and birth defects (over 30 published studies involving more than 130,000 patients), Dr. Lamm concluded that there was no statistically significant association between Bendectin and birth defects in general, or limb reduction birth defects in particular. Pet. App. A2. Petitioners opposed summary judgment, proffering the contrary opinions of eight experts. Those experts based their opinions on: (1) *in vitro* (test tube) and *in vivo* (animal teratology) tests, chemical structure analyses; and (2) in three instances (Drs. Gross, Swan, and Glasser), "reanalysis" of data from the published epidemiological studies relied on by Merrell Dow. *Id.* at A9, A11-A13.

The district court granted Merrell Dow's motion for summary judgment. Pet. App. A6-A15. Because Merrell Dow was the movant, the district court viewed "the evidence in a light most favorable to [petitioners]" to determine "whether a fair-minded jury could return a verdict for the [petitioners] [based] on the evidence presented." *Id.* at A7, quoting *Anderson* v. *Liberty Lobby, Inc.*, 477 U.S. 242, 251-252 (1986). But because petitioners bore the ultimate burden of proof on the issue of causation at trial, the district court held that the evidence favoring petitioners had to raise a material question as to whether Merrell Dow's conduct "was more probably than not the proximate cause of the accident." Pet. App. A7-A8.

Assessing the evidence under those standards, the district court found it insufficient to withstand summary judgment. Pet. App. A13-A15. The *in vitro* and *in vivo* tests and the chemical structure analyses were insufficient by themselves absent epidemiological studies—*i.e.*,



studies showing a link between Bendectin and fetal malformations in human beings, rather than merely test-tube chemical reactions or animal reactions to highly-concentrated amounts of a chemical. *Id.* at A9 ("causation may be shown only through reliance upon epidemiological evidence"); see also *id.* at A13-A14. Thus, the animal and chemical studies "lack[ed] the sufficient foundation necessary under [Fed. R. Evid.] 703" for admission into evidence and were "insufficient to take the issue [of causation] to the jury." *Ibid.*

The district court also found insufficient the "reanalysis" of epidemiological data by Drs. Gross, Swan, and Glasser. Pet. App. A14-A15. First, the district court rejected Dr. Gross's "study" because, *inter alia*, "nowhere [did] it state that Bendectin sales increased the relative risk of limb reduction defects to a level significantly above 1.0 with a confidence interval that did not include unity," *id.* at A15—*i.e.*, in statistical terms, Dr. Gross's work, even if admissible, showed no statistically significant relationship between Bendectin and fetal malformation. Second, the district court found Dr. Swan's "unsupported allegations" of a "statistically significant" connection between Bendectin and limb defects "similarly insufficient." Finally, the court adverted to the Fifth Circuit's *Brock* opinion, in which that Court noted that Dr. Glasser, while finding a "relative risk of 1.49" for Bendectin in his study, "admit[ted] that the confidence interval was from 0.17 to 3 * * * render[ing] the study statistically insignificant." *Id.* at A14-A15, citing *Brock* v. *Merrell Dow Pharmaceuticals, Inc.*, 874 F.2d at 312-313. "[T]he strongest inference to be drawn for [petitioners]," the district court concluded, "is that Bendectin could possibly have caused [their] injuries," a claim insufficient to take this matter to the jury. *Ibid.*

3. The court of appeals affirmed. Pet. App. A1-A5. Stating that "[e]xpert opinion based on a scientific technique 'is admissible if it is generally accepted as a reliable

technique among the scientific community.'" *Id.* at A2, citing, *inter alia*, *Frye* v. *United States*, 293 F. 1013, 1014 (D.C. Cir. 1923), the court of appeals held that petitioners could not establish causation "in the absence of critically analyzed epidemiological studies establishing a connection between the use of the drug and the birth defects." Pet. App. A3. The court agreed with the district court that petitioners had failed to present such evidence. The "animal and chemical studies were insufficient" because of the "need to verify such data with epidemiological evidence." *Ibid.* The "reanalyses" of the epidemiological data were also insufficient because the studies "were unpublished, not subjected to the normal peer review process and generated solely for use in litigation." *Id.* at A5. Because petitioners' offerings "provide insufficient foundation to allow admission of expert testimony to the effect that Bendectin caused [petitioners'] injuries," petitioners "could not satisfy their burden of proving causation at trial" and, thus, summary judgment was appropriately entered against them. *Ibid.*

## SUMMARY OF ARGUMENT

The Federal Rules of Evidence provide ample authority for a federal court to "screen" expert opinion testimony and to exclude such evidence if it is insufficiently reliable, or if it would unfairly mislead or confuse the jury. The district court properly exercised that authority in this case. While the court of appeals' reasoning was considerably broader than necessary to resolve this case—insofar as it relied on the restrictive *Frye* rule as the exclusive test for the admissibility of expert scientific testimony—its judgment affirming the district court was correct.

1. Rules 702 and 703, in conjunction with Rule 403, set forth the standards governing the admissibility of scientific expert opinion in federal court. Rule 702 provides that, in addition to demonstrating that he has rele-



vant training or experience, a witness proffered as an expert must testify to "scientific, technical or other specialized *knowledge*" that will "*assist*" the trier of fact to discharge its duties in the instant case. Petitioners' submission that the trial court lacks authority to exclude evidence it finds unreliable disregards the Rule's command that a witness must testify to "knowledge" that will "assist" the trier of fact, not to unsubstantiated hypotheses or theories. In light of Rule 702's broad purpose of assisting the jury, we read the requirement of knowledge broadly as embodying not only irrefutable certitudes but also facts that can be established with a sufficient level of reliability to be helpful to the jury's determinations of the issues in a particular case. The rule of *Frye* v. *United States*, 293 F. 1013 (D.C. Cir. 1923), which requires "general acceptance" of a principle before evidence based on it may be admitted, has some usefulness in fulfilling that purpose—a trial judge cannot err by *admitting* testimony that is based on the unexceptionable application of universally accepted principles. We believe, however, that the *Frye* rule is too limiting to serve as a rule of exclusion in all circumstances. Thus, while we agree that Rule 702 requires a careful examination of the reliability of expert scientific evidence in light of the purpose for which it is offered (as all courts of appeals that have considered the question have concluded), we also agree with the minority view that the inquiry should be guided by a broader range of factors than those suggested by the strict *Frye* formulation.

In the ordinary case, the factors informing whether an expert's testimony is sufficiently reliable to be of assistance will include: (1) whether the technique relied on by the expert has achieved acceptance by at least a significant minority within the field; (2) whether the potential rate or possibility of error can be estimated (and the extent to which any uncertainty on this score would tend to favor the opponent of the evidence); (3) the degree to which subjectivity in the analysis renders

intelligent evaluation of the expert's conclusions impractical, requiring the trier to take the conclusions "on faith"; and (4) the extent to which the expert has exposed his methodology or conclusions to peers through publication or otherwise. The first factor will often be dispositive in cases where a methodology has been tested for a significant period of time, since a known technique which has been able to attract at most minimal support from those most likely to possess the ability to identify its flaws can be presumed to be unreliable. The court may admit expert testimony that relies on a scientific technique that is so novel that it has not yet been widely examined by those best qualified to identify its failings, but only in circumstances that assure its reliability in light of the purpose for which it is offered. When, as here, the technique relies on statistical analysis, its proponent must carry the burden of showing not only an objectively ascertainable margin of error, but also that the margin of error is significantly lower than what ordinarily would be expected from the operation of chance alone.

2. Our view that Rule 702 incorporates a "reliability" requirement is supported not only by the plain language of that Rule, but also by the related requirements of Rule 703. Rule 703 authorizes experts to testify to conclusions or inferences based on "facts or data" not admissible in evidence, but only if such "facts or data" are "of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject." The Advisory Committee notes make clear that a district judge applying that rule should concentrate "on the validity of the techniques employed" by such a "hearsay" expert. We believe it implausible to suggest that the Rules of Evidence were intended to require courts to examine the validity of scientific techniques *only* when those techniques are used by such "hearsay" experts, leaving other expert witnesses completely free to give testimony based on unfounded theories. It is far more



sensible to view Rule 703 simply as extending to the testimony of hearsay experts the same requirements of trustworthiness that the drafters expected would be applied to expert testimony generally.

3. Evidence that satisfies the admissibility standards of Rules 702 and 703 may nonetheless be excluded under Rule 403, which vests the trial judge with discretion to prevent the jury from misusing otherwise admissible relevant evidence. Thus, expert testimony that may otherwise be sufficiently reliable for a limited purpose can be excluded when it is likely to confuse or mislead the jury about related issues for which it is not sufficiently reliable to be independently admissible, or when it has an undue tendency to suggest decision on an unsubstantiated, rather than a rational, basis.

4. There is no support in the Federal Rules of Evidence for petitioners' overriding thesis that the rules evince a plan to leave entirely to the jury the task of assessing the reliability of expert testimony, without any preliminary "screening" function for the court. The Rules themselves clearly provide that all questions concerning the admissibility of evidence must "be determined by the court." Fed. R. Evid. 104(a). This Court has made clear that this broad authority encompasses the responsibility to decide conclusively preliminary questions of fact on which the admissibility of evidence depends. See *Bourjaily* v. *United States*, 483 U.S. 171 (1987). Whether evidence is sufficiently reliable to qualify as "knowledge" under Rule 702, no less than whether the factual predicate for admissibility under a hearsay exception has been shown, is just such a preliminary question that the rules reserve for the trial judge.

5. Assessed under the foregoing principles, the court of appeals' conclusion that the testimony of petitioners' experts was too unreliable to be admissible under the federal rules was correct. Petitioners' "reanalysis" of published epidemiological studies produced statistically insignificant results—*i.e.*, to the extent their findings for

the exposed population departed from the corresponding "expected" values, the degree of departure was consistent with what a researcher would expect based solely on the chance variability of the sampling procedure. Because scientific norms generally require that results be statistically significant to be considered reliable, petitioners bore a heavy burden to demonstrate that the proffered testimony was probative even without satisfying those norms. Petitioners failed to meet that burden. Their epidemiological evidence accordingly had no probative value in demonstrating even a general *association* between Bendectin and fetal malformation, much less that that drug more probably than not was the *cause* of petitioners' injuries. Without reliable epidemiological data, petitioners' remaining evidence (consisting of various *in vitro* and *in vivo* animal tests, together with chemical structure analyses), was insufficient as a matter of law to support a finding that Bendectin caused the birth defects at issue in this case. In these circumstances, summary judgment was appropriately entered against petitioners, and the decision below should be affirmed.

## ARGUMENT

### THE COURTS BELOW PROPERLY EXCLUDED THE EVIDENCE OF CAUSATION PROFFERED BY PETITIONERS AND CORRECTLY ENTERED JUDGMENT AGAINST THEM

This case concerns the correct standard for determining the admissibility of expert scientific testimony. The majority of the courts of appeals hold that the admissibility of such evidence is governed by the test first articulated in *Frye* v. *United States*, 293 F. 1013 (D.C. Cir. 1923).[3] *Frye* held that expert testimony based on a

[3] See, *e.g.*, *Daubert* v. *Merrell Dow Pharmaceuticals, Inc.*, 951 F.2d 1128 (9th Cir. 1991) (opinion below); *Christophersen* v. *Allied-Signal Corp.*, 939 F.2d 1106, 1110-1111, 1115-1116 (5th Cir. 1991) (en banc), cert. denied, 112 S. Ct. 1280 (1992); *United States* v. *Smith*, 869 F.2d 348, 351 (7th Cir. 1989); *United States* v. *Shorter*, 809 F.2d 54, 59-60 (D.C. Cir.), cert. denied, 484 U.S. 817 (1987); *United States* v. *Metzger*, 778 F.2d 1195, 1203 (6th Cir. 1985), cert. denied, 477 U.S. 906 (1986); *United States* v. *Smith*, 776 F.2d 892, 898 (10th Cir. 1985); *United States* v. *Alexander*, 526 F.2d 161, 163-164 (8th Cir. 1975).



scientific technique is admissible only if there has been a preliminary showing that the technique has gained general aceptance in the particular field in which it belongs. See *Frye* v. *United States*, 293 F. at 1014. The Second, Third, Fourth, and Eleventh Circuits, on the other hand, have rejected the holding of *Frye* in favor of a more generalized inquiry into the relevance and reliability of the expert evidence. In those four circuits, the trial judge may nonetheless exclude scientific evidence that he finds insufficiently reliable to aid the jury in resolving the issues in the case.[4]

Petitioners endorse the minority view insofar as it rejects the holding of *Frye*. Petitioners reject, however, any suggestion that a federal trial court may exclude otherwise relevant expert testimony based on its own preliminary conclusion that the methodology employed by the witness is not sufficiently reliable to be of assistance to the jury. Petitioners therefore disagree with the unanimous conclusion of the courts of appeals that *some* independent preliminary inquiry into the reliability of a scientific technique—whether under *Frye* or a more relaxed standard—is required by the federal rules. In petitioners' view, once a witness is shown to have some training in an area generally pertinent to the subject matter of the litigation, the jury alone must be entrusted with the determination whether the witness's methodology and

[4] See, *e.g.*, *United States* v. *Jakobetz*, 955 F.2d 786, 793-797 (2d Cir.), cert. denied, 113 S. Ct. 104 (1992); *United States* v. *Piccinonna*, 885 F.2d 1529, 1536-1537 (11th Cir. 1989); *United States* v. *Downing*, 753 F.2d 1224, 1237-1240 (3d Cir. 1985); *United States* v. *Baller*, 519 F.2d 463, 465-466 (4th Cir.), cert. denied, 423 U.S. 1019 (1975).

conclusions are reliable. Pet. Br. 15, 32-33, 39-40. We disagree. For the reasons that follow, the Federal Rules of Evidence require trial courts to determine independently, as a preliminary matter, whether a scientific process or method is sufficiently reliable to be helpful in determining a fact in issue.

### A. Under The Rules Of Evidence, An Expert Witness May Testify Only To "Knowledge" That Is Sufficiently Reliable To Assist The Trier Of Fact

1. Rules 702 and 703, together with Rule 403, provide the framework for the admissibility of expert testimony. The starting place for our discussion is Rule 702. Because the Federal Rules of Evidence are a legislative enactment, we must "turn to the 'traditional tools of statutory construction' in order to construe their provisions." *Beech Aircraft Corp.* v. *Rainey*, 488 U.S. 153, 163 (1988) (citations omitted). Our analysis therefore begins with the language of Rule 702. *Ibid.*; see also *Huddleston* v. *United States*, 485 U.S. 681, 687 (1988). That language is clear. In addition to a showing that the witness has relevant training or experience, an individual proffered as an expert must testify to "scientific, technical or other specialized *knowledge*" that will "*assist*" the jury to discharge its duties in the instant case.

The principal flaw in petitioners' analysis of Rule 702 is that it ignores the requirement that the subject of the witness's testimony be helpful "knowledge." The rule does not define that term and, accordingly, absent some clear indication to the contrary, it must be given its ordinary meaning. *Chapman* v. *United States*, 111 S. Ct. 1919, 1925-1926 (1991); *Russello* v. *United States*, 464 U.S. 16, 21 (1983). In ordinary parlance, "knowledge" refers to the "sum total of what is known, the whole body of truth, fact, information, principles, or other objects of cognition acquired by mankind," or to "the fact or condition of apprehending truth, fact, or reality immediately with the mind or senses." *Webster's Third*



*New International Dictionary* 1252 (1986). Rule 702's requirement that the expert witness testify to what is "known" excludes mere unsubstantiated hypotheses or theories, however sincerely the witness may believe them.

The concept of "knowledge" about a subject, however, does not necessarily encompass only irrefutable certitudes. It would be sensible in certain contexts to refer more broadly to what is "known," as that which has been satisfactorily established for a given purpose. See *Webster's II New Riverside University Dictionary* 669 (1988). We believe that that broader meaning is more consistent with the context in which the word "knowledge" appears in Rule 702. In light of the requirement that the evidence be of such character as will "assist" the jury "to understand the evidence or to determine a fact in issue," we believe the requirement of "knowledge" should be understood to refer to the body of propositions that are at least sufficiently established to serve that purpose.

The rule of *Frye* v. *United States*, *supra*, is too limiting to serve as the exclusive test for what constitutes helpful knowledge in that broad sense. To be sure, a trial judge cannot err by *admitting* testimony that is based on the unexceptionable application of universally accepted scientific principles. But the *Frye* rule is too restrictive to serve as the sole criterion when the issue is whether evidence should be *excluded*. Evidence based on new discoveries may be demonstrably reliable on the basis of objective criteria easily understood by a trial judge. Moreover, even a body of assertions generally viewed as manifestly unreliable, untrue or even superstitious for most purposes may be sufficiently reliable to be helpful in certain limited circumstances. Thus, while a judge would err in admitting the testimony of an astrologer to prove that certain events must have occurred as predicted by the horoscope, he would be justified in admitting testimony from the same witness in order to explain the pattern underlying the crimes of a zodiac

killer. Similarly, evidence that is not sufficiently reliable to be considered helpful in proving the truth of a disputed fact may be reliable enough to impeach or corroborate the reliable evidence that *is* admissible to prove the point. Cf. *Michigan* v. *Harvey*, 494 U.S. 344, 350-351 (1990); *Oregon* v. *Haas*, 420 U.S. 714, 720-724 (1975). An epidemiological study that produces statistically insignificant results, for example, might properly be used for the limited purpose of casting doubt on a more definitive study on the same question, provided the jury receives a suitable limiting instruction. See Fed. R. Evid. 105. In sum, we believe that the *Frye* test is not sufficiently flexible to deal satisfactorily with the manifold circumstances in which specialized knowledge may be of assistance to the jury. We are therefore in agreement with those courts of appeals that have abandoned exclusive reliance on *Frye* in favor of a more generalized inquiry into the reliability of the evidence in light of the purpose for which it is offered. See *DeLuca* v. *Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d at 954 ("expert testimony that is based on unreliable methodology is unhelpful and therefore excludable"); see also *United States* v. *Jakobetz*, 955 F.2d at 796.

The factors bearing on the court's determination of reliability will necessarily vary depending on the purpose for which the evidence is being offered, a matter that in turn may often depend on the requirements imposed by the relevant substantive law.[5] In the usual case involving

[5] Important environmental statutes, for example, require certain actions to be taken upon a showing that a condition creates "danger" or a "risk" of a specified consequence. See, *e.g.*, 42 U.S.C. 9606(a) ("substantial endangerment to the public health or welfare or the environment"); 42 U.S.C. 6973(a) ("upon receipt of evidence that the * * * handling, storage, treatment, transportation or disposal of any solid waste or hazardous waste may present an imminent and substantial endangerment to health or the environment, the Administrator may bring suit * * * to restrain such person * * * contributing to such handling, storage, treatment, transportation or disposal"). In such circumstances, expert testimony showing that the scientific community is sharply divided on whether the condition actually produces the specified consequence plainly would be reliable enough to be considered on the issue whether a *risk* can be demonstrated. Similarly, the governing substantive law may provide that the existence of pertinent facts must be established by reference to the latest available technology, even where that technology is in a purely developmental stage. Thus, the Clean Air Act requires that new facilties or existing facilities making major modifications demonstrate utilization of either the "best achievable [control] technology," or the "lowest achievable emission rate," depending upon whether the geographic area in which the facility is located has met primary and secondary ambient air quality standards for a given pollutant. See 42 U.S.C. 7475(a) (requiring installation of best available technology in new sources in "attainment" areas and "unclassifiable" areas); 42 U.S.C. 7479(3) (defining best available control technology); 42 U.S.C. 7501(3) (defining lowest achievable emission rate). Again, in such cases, the applicable substantive law establishes what is helpful in "determin[ing the] fact in issue." Fed. R. Evid. 702.



whether the existence of a fact can be demonstrated by the proponent, courts will ordinarily determine reliability by considering: (1) whether the technique at issue has achieved substantial acceptance by at least a significant minority within the field; (2) whether the potential rate or possibility of error can be estimated (and the extent to which any uncertainty on this score would tend to favor the opponent of the evidence); (3) the degree to which subjectivity in the analysis renders intelligent evaluation of the expert's conclusions impractical, requiring the trier to take the conclusions "on faith"; and (4) the extent to which the expert has exposed his methodology or conclusions to peers through publication or otherwise. See *United States* v. *Jakobetz*, 955 F.2d at 794, 797-798; *United States* v. *Downing*, 753 F.2d at 1238-1239; *United States* v. *Gould*, 741 F.2d 45, 49 n.2 (4th Cir. 1984); *United States* v. *Baller*, 519 F.2d at 466; see generally 3 J. Weinstein & M. Berger, *Weinstein's Evidence* ¶ 702[03], at 702-41 to 702-43 (1992) (collecting authorities).

We believe that courts should look principally to the first of these factors—the degree to which scientists have accepted the methodology—as a means of testing reliability in most cases. Judges are not better qualified to assess scientific methods than the scientific community as a whole, and they may properly view with great skepticism "a known technique which has been able to attract only minimal support within the community." *United States* v. *Downing*, 753 F.2d at 1238; see also *United States* v. *Williams*, 583 F.2d 1194, 1198 (2d Cir. 1978) ("[A] technique unable to garner *any* support, or only minuscule support, within the scientific community would be found unreliable by a court."), cert. denied, 439 U.S. 1117 (1979); 3 J. Weinstein & M. Berger, *supra*, ¶ 702[03], at 702-41 to 702-42. When a scientific technique is so novel that it has not yet been widely examined by those best qualified to identify its failings—the experts in the field—the court may admit expert testimony that relies on that technique, but only in circumstances that assure its reliability in light of the purpose for which it is being offered. See, *e.g.*, *United States* v. *Baller*, 519 F.2d at 466. If, as in this case, a scientific technique relies on statistical analysis, the proponent of the evidence must carry the burden of showing not only that the technique has an ascertainable margin of error (thereby enabling the court and the jury to weigh it intelligently), but also that the margin of error is significantly lower than what ordinarily would be expected from the operation of chance alone. A technique whose reliability is so low as to be essentially indistinguishable from throwing a die or tossing a coin cannot be the basis for rational judgment, and cannot be of assistance to the jury.

2. Our submission that a scientific methodology or technique can be considered helpful "knowledge" under Rule 702 only if that methodology or technique meets a threshold test of reliability draws additional support from Rule 703, which governs the "bases of opinion testimony



by experts." Rule 703 provides that an expert may testify to conclusions or inferences based on "facts or data" not admissible in evidence, but only if such "facts or data" are "of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject." Petitioners correctly note that Rule 703 applies only to expert witnesses who testify on the basis of hearsay evidence instead of their own first-hand observations—a subset of all expert witnesses. Pet. Br. 35. Petitioners err, however, in suggesting both that Rule 703 does not speak at all to the reliability of the methodology used by such "hearsay" experts, and that the Rule tells us nothing about the criteria for the admissibility of other expert testimony. Pet. Br. 35-37.

As to the first point, the Advisory Committee notes explain that Rule 703 is intended to "broaden the basis for expert opinions * * * and to bring the judicial practice into line with the practice of experts themselves when not in court." See Rule 703, Adv. Comm. Note. As an example, the notes refer to "a physician [who] in his own practice bases his diagnosis on information from numerous sources and of considerable variety," and who "makes life-and-death decisions in reliance upon them." *Ibid.* The physician's willingness to make such weighty decisions, however, would presumably disappear if he were required to make them based on a capriciously selected subset of the data—*e.g.*, based on patient charts from which every third entry had been deleted. That example therefore suggests that, contrary to petitioners' theory, the manner in which the facts or data are arranged—that is, the expert's method in approaching the facts or data—must itself be reliable. That conclusion is confirmed by the second example provided by the Advisory Committee, which deals with admissibility of evidence of public opinion polls. For such evidence—which relies on statistical sampling techniques very similar to those at issue in this case—the Advisory Committee expressly coun-

sels that attention should focus on "*the validity of the techniques* employed." *Ibid.* (emphasis added).

As to petitioners' second point, given that the Advisory Committee notes expressly advert to the court's authority to examine the "validity of the techniques employed" by hearsay experts, it is implausible to suggest that the drafters intended that courts would perform that function *only* for those experts, leaving other expert witnesses completely free to give testimony based even on patently absurd theories. It is far more sensible to interpret Rule 703 simply as extending to the testimony of hearsay experts the same requirements of trustworthiness otherwise required for expert testimony generally.[6] That is particularly so in light of the nearly unanimous view—requiring *some* inquiry into the foundation of scientific evidence, *e.g.*, P. Giannelli, *The Admissibility of Novel Scientific Evidence*, 80 Colum. L. Rev. 1197, 1229 (1980)—that confronted the drafters of the Federal Rules of Evidence. See *United States* v. *Abel*, 469 U.S. 45, 50-51 (1984). While it is clear enough from the language of the rules that the drafters intended to "*relax*[] the traditional barriers to 'opinion' testimony," most notably by eliminating the exclusion of opinions on "ultimate issues," *Beech Aircraft Corp.* v. *Rainey*, 488 U.S. 153, 169 (1988) (emphasis added), the proposition that they silently *eliminated* all those barriers completely, as petitioners would have it, is not only "unlikely," *United States* v. *Abel*, 469 U.S. at 50, but also basically irreconcilable with the very existence of the rules contained in Article VII of the Federal Rules of Evidence.

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[6] Indeed, there is very little particularly relevant scientific evidence that does not depend on hearsay. Most witnesses who would testify solely to the results of their own research would nonetheless necessarily rely on principles and studies—"facts or data"—developed by other scientists. In that sense, most expert opinions rely on other research, aside from the precise findings of a particular study, that are part of the "hearsay" body of scientific knowledge.



3. The general admissibility standards in the Federal Rules of Evidence provide other limitations, in addition to the requirements of Rules 702 and 703, that prevent the admission of otherwise logically relevant evidence. The most important limitation is Rule 403, which provides that relevant evidence "may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence." Fed. R. Evid. 403. A district court "is accorded wide discretion in determining the admissibility of evidence" under this Rule. *United States* v. *Abel*, 469 U.S. at 54.

As petitioners concede (Pet. Br. 38-39), the general restrictions imposed by Rule 403 apply to expert testimony no less than to other types of evidence. According to the Advisory Committee notes accompanying Rule 403, the Rule authorizes exclusion of evidence where a jury might be substantially misled or confused by it, especially when the evidence tends "to suggest decision on an improper basis, commonly, though not necessarily, an emotional one." Rule 403, Adv. Comm. Note. In our view, expert testimony that is otherwise minimally reliable for a narrow, limited purpose may appropriately be excluded under Rule 403 when it is likely to confuse or mislead the jury about related issues for which it is not sufficiently reliable to be independently admissible, or when its limited relevance will be substantially outweighed by its tendency to induce an emotional, rather than a rational, judgment. Exercise of the broad authority conferred by Rule 403 may also be appropriate when a party proposes to meet his entire burden of proof through abstruse expert testimony which is at best only minimally reliable, in a case so likely to be dominated by appeals to sympathy as to create "a very real possibility of runaway emotion overcoming judgment." See, *e.g.*, *Lynch* v. *Merrell-National Laboratories*, 830 F.2d 1190, 1196-1197 (1st Cir. 1987).

4. We fundamentally disagree with a recurring theme of the argument pressed by petitioners and their amici: that the Rules of Evidence evince a plan to leave *entirely* to the jury the task of assessing the reliability of expert testimony, without any preliminary "screening" function for the court. See Pet. Br. 15, 38-40; Trial Lawyers' Amicus Br. 6-12. The Rules themselves clearly provide that all questions concerning the admissibility of evidence must "be determined by the court." Fed. R. Evid. 104(a). As this Court has made clear, that broad authority encompasses the responsibility to decide conclusively preliminary questions of fact on which the admissibility of evidence depends. See *Bourjaily* v. *United States*, 483 U.S. at 175-176 (in applying co-conspirator exception to hearsay rule, the court alone decides preliminary question of whether conspiracy existed).[7] Whether evidence

[7] We see no basis for applying a different rule when, as here, the exercise of the court's authority under Rule 104(a) "non-suits the plaintiffs." Pet. Br. 39 n.68. As Professor Morgan aptly explained in a leading article more than 60 years ago:

> It often happens that the only evidence that a litigant has to support his case is incompetent either by statute or by a rule of the common law. Where its incompetency does not depend upon the decision of a preliminary question of fact, no court allows itself to be influenced by this consideration. Granting the validity of the exclusionary rules, there is no plausible or substantial reason for discriminating between such cases and those where a preliminary investigation is necessary. The accepted theory of jury trial requires that there be submitted to the jury only matters in dispute as to which reasonable men could differ, and that in resolving the dispute the jury shall hear only legal evidence. There never was a time when every question of fact arising in a lawsuit was to be decided by the jury: nor has there been a time since the jury has been required to base its findings upon evidence submitted in open court, when it has been privileged to hear and consider all relevant evidence.

E. Morgan, *Functions of Judge and Jury in the Determination of Preliminary Questions of Fact*, 43 Harv. L. Rev. 165, 186 (1929); see generally E. Imwinkelried, *Judge Versus Jury: Who Should Decide Questions Of Preliminary Facts Conditioning The Admissibility Of Scientific Evidence?*, 25 Wm. & Mary L. Rev. 577 (1984).



is sufficiently reliable to qualify as "knowledge" under Rule 702, no less than whether the factual predicate for admissibility under a hearsay exception has been shown, is just such a preliminary question. Indeed, petitioners' contrary theory would invite extravagant efforts to introduce on behalf of defendants in criminal cases wholly unsubstantiated and speculative hypotheses, under the guise of expert scientific testimony, in an attempt to influence the jury's application of the reasonable doubt standard.[8]

Nor is there force to petitioners' argument that the doctrine of *Erie R. R.* v. *Tompkins*, 304 U.S. 64 (1938), requires that the reliability of expert testimony be left exclusively to the jury at least in diversity cases. Pet. Br. 41-46. That contention is largely based on the unwarranted assumption that abandoning the *Frye* test necessarily leaves federal courts without authority to screen the reliability of scientific testimony. As demonstrated above, and as every court to reject *Frye* has held, Rules 702, 703, 403 and 104(a) require trial courts to make an independent assessment of the reliability of scientific

[8] Petitioners' reliance on *Barefoot* v. *Estelle*, 463 U.S. 880 (1983), is misplaced. That case, which involved the constitutionality of a state evidentiary rule permitting the admission of expert psychiatric testimony on the issue of the future dangerousness of a particular person, necessarily turned on the peculiar nature of the issue on which the testimony was offered. As the Court noted, future dangerousness is the type of issue ordinarily resolved sensibly by lay people, so that it would "make little sense, if any, to submit that psychiatrists, out of the entire universe of persons who might have an opinion on the issue, would know so little about the subject that they should not be permitted to testify." *Id.* at 896-897. Contrary to petitioners' submission (Pet. Br. 39-40), the Court did not purport to decide authoritatively any issue under the Federal Rules of Evidence. On the contrary, the Court rejected a number of arguments advanced in dissent because they were based on "decisions of federal evidence law." 463 U.S. at 899 n.6.

evidence before such evidence can be submitted to the jury. Because the rules clearly speak to the issue, no *Erie* issue is presented. See *Hanna* v. *Plumer*, 380 U.S. 460 (1965) (substantially modifying "outcome-determinative" test of *Guaranty Trust Co.* v. *York*, 326 U.S. 99 (1945), on which petitioners rely); see also *Stewart Org., Inc.* v. *Ricoh Corp.*, 487 U.S. 22, 25-27 (1988). Indeed, it is quite doubtful that petitioners could succeed on their *Erie* theory even if the allocation of that traditional screening function to the court were the result of a judge-made rule. See *Byrd* v. *Blue Ridge Rural Elec. Coop., Inc.*, 356 U.S. 525, 537-538 (1958) ("The policy of uniform enforcement of state-created rights and obligations * * * cannot in every case exact compliance with a state rule * * * which disrupts the federal system of allocating functions between judge and jury.").

In sum, petitioners' fundamental premise—that rejection of the *Frye* test necessarily deprives the district courts of *any* authority to exclude unreliable testimony—is inconsistent with the language of Rules 702, 703, 403 and 104(a). Not surprisingly, petitioners' view has failed to gain any support even among the minority of courts of appeals that have rejected *Frye*. The language of those Rules makes clear that, under any formulation of the tests for assessing the admissibility of expert testimony, trial judges retain ample authority and are vested with the responsibility to exclude such testimony when it is insufficiently reliable to be helpful to the jury.

### B. The Trial Court Properly Excluded The Expert Testimony Proffered By Petitioners In This Case

The court of appeals examined the admissibility of petitioners' evidence under the *Frye* rule, which it appeared to view principally as a specific application of the criteria outlined in Rule 403. See Pet. App. A2. As we have explained, it is our view that the *Frye* rule is too narrow to serve as the exclusive standard for the admissibility of expert testimony. Despite our disagreement with



the analysis employed by the court of appeals, we believe its conclusion was correct. The testimony of petitioners' experts was too unreliable to be admissible under the Federal Rules. In fact, as the district court's opinion demonstrated, and as several courts of appeals correctly have held, the methodology used by petitioners' experts was so lacking in probative value that judgment for the respondent was required as a matter of law even if the evidence had been admitted.

Petitioners' "proof" on the issue of causation fell under two main headings. First, petitioners relied on the "reanalysis" of the published epidemiological studies by three of their experts—Drs. Gross, Swan, and Glasser. The district court specifically found that those reanalyses lacked a confidence level which would render them statistically significant. Because scientific norms generally require that results be statistically significant to be considered reliable, petitioners bore a heavy burden to demonstrate that the reanalysis evidence was probative despite its failure to meet those norms. Petitioners did not, and could not, do so. To the extent the findings for the exposed population departed from the corresponding expected values, the degree of departure was consistent with what a researcher would expect based solely on the chance variability of sampling procedures. Petitioners' reanalysis evidence accordingly has no probative value in demonstrating an association between Bendectin and fetal malformation, much less that that drug "more probably than not" was the "cause" of petitioners' injuries. From the standpoint of reliability for purposes of the substantive issue in this case, those studies are not significantly better than a coin toss, and therefore could not provide a basis for expert opinion on the issue of causation.

Second, petitioners also relied on *in vitro* and *in vivo* animal tests, together with chemical structure analyses. We agree with petitioners that such tests may be useful in some limited contexts (Pet. Br. 6 nn.. 17-18), particularly in connection with *risk assessment—i.e.*, whether,

on the basis of often incomplete information, the policy considerations embodied in the substantive law counsel the taking of particular action prospectively. Cf. 21 U.S.C. 348(c)(3)(A) (so-called "Delaney Clause," which provides that "no [food] additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal"). The issue in this tort case, however, is significantly different. The courts below were asked to decide whether respondent's drug actually "more likely than not" caused tort injury to particular human beings. For this purpose, that type of evidence is not even logically relevant absent a foundation that at least establishes not only that human beings behave similarly to the tested animal species when exposed to a chemical, but also that the high concentrations of the chemical generally used in animal studies permit a rational extrapolation to the much lower levels to which petitioners were actually exposed. Doubtless for that reason, even petitioners' experts acknowledged the need to verify such data with epidemiological evidence. Pet. App. A3; see also *id.* at A9-A10, A13-A14. Without corroborating epidemiological evidence, those non-human studies were not "facts or data * * * of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject," Fed. R. Evid. 703, and the court of appeals therefore properly found them inadmissible. See Pet. App. A3, A9-A10, A12, A13-A14.



## CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted.

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* The Solicitor General is disqualified in this case.

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